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10/602,446	06/24/2003	Kelly S. Stack	STK-001	9380

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/602,446	Applicant(s) STACK, KELLY S.	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/22/2007 has been entered.

Response to Arguments

2. Some of the arguments filed 2/22/2007 are moot in view of new grounds of rejection but the examiner has responded to the Applicant's arguments filed 2/22/2007 that are still applicable to the rejections presented in this office action.

3. Applicant argues that Wilson (US 2004/0098073) only discloses attaching the device to a child's wrist and does not make obvious attaching the device to an infant's wrist. The examiner believes that applicant's interpretation of a child as mentioned in Wilson is too narrow. No ages are indicated in the instant specification for the term "infant" and it seems to the examiner that a 1 yr old, for example, could be called a child or an infant. Furthermore, no indication of the fit of the bracelet or any dimensions are present in the claims. Independent claim 1 only indicates that the bracelet is "adapted to be attached around an infant's wrist". If the device of Wilson can attach to a child's wrist, it can be put around an infant's wrist. Also, the wrist of a very small three or four-year old may be the same size as the wrist of a large 18-month old.

4. Applicant also argues that there is nothing in the references of Wilson that suggests sucking on the capsules which fill the device. However, the language "adapted to be sucked on"

means that it can be sucked on and therefore limits the device only so far as that the user can suck on the device. With this language, the references do not need to disclose the step of sucking on the capsules. Regarding the method claim 11, the limitation of the actual step of sucking on the capsule is not included, only that it "is adapted to allow the infant to suck on the capsule". The device of Wilson has pea size capsules and even when covered by material, can certainly be sucked on through the fabric. It is noted that the phrase "adapted to be sucked on" does not add any size limitation. In other words, a person can suck on their arm or a breath-mint. Sucking on something is not limited to having the entire item in your mouth.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-4, and 7-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Cipolla (U.S. 5,458,628) and Rucki (U.S. 5,679,052). Wilson discloses an apparatus comprising a bracelet, the bracelet enclosing a volume and adapted to be attached around an infant's wrist (fig. 5a), wherein the bracelet has a wrist-facing side and an outer side opposite the wrist facing side. The examiner is considering a child to include an age range that includes infants. No ages are indicated in the instant specification for the term "infant" and it seems to the examiner that a 1 yr old, for example, could be called a child or an infant. The bracelet is made of a polyurethane film, which is considered a fabric since a fabric can be broadly defined as any pliable material. and is made of a non-absorbent fabric. The bracelet

contains a plurality of capsules ([0042]) within the volume, wherein each of the plurality of capsules contains a substance that is liquid at room temperature and wherein the bracelet is adapted to allow the infant to suck on one of the plurality of capsules through the fabric. The language "is adapted to allow" is functional language and necessitates that bracelet is capable of allowing an infant to suck on one of the plurality of capsules through the fabric. Polyurethane film is usually non-absorbent but Wilson does not expressly disclose that the polyurethane film used in his invention is non-absorbent.

7. However, Cipolla discloses that it is old and well known to cover therapeutic temperature pads with a nonabsorbent material. Such a cover provides for ease of cleanup of the covers and for better heat/temperature and water retention of a pad contained therein. Non-absorbent materials also help avoid staining of the material and foul odors. Using non-absorbent polyurethane film for the device of Wilson would increase the amount of cooling time the bracelet can provide and would also help avoid contamination of the bracelet material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Wilson to include non-absorbent polyurethane film such that bracelet material can be easily cleaned and remains cooler longer as made obvious by Cipolla.

8. Wilson also fails to disclose plural layers of fabric on the wrist-facing side of the device that cannot be detached from one another. However, Rucki discloses that it is old and well known to provide a second layer of material on the patient facing side of the cold therapy device in order to prevent too much cold from being directly applied to the patient (see col. 2 ll. 56-63). This layer is heat-sealed around its edges which would prevent it from being detached from the other layer of the bracelet. Therefore, it would be obvious to one of ordinary skill in the art to apply a second layer of fabric on the wrist facing side of the device of Wilson in order to protect the patient from possible frost-bite.

9. Regarding claim 2, Wilson et al. discloses that the material is flexible and stretches and is therefore, elastic. Necessarily, when the bracelet is attached to the wearer's hand, the bracelet is stretched to pass over the hand. When this stretching occurs, the inner circumference is inherently increased.

10. Regarding claim 3, Wilson does not expressly disclose that the water-filled capsules have a rigid covering. However, Wilson further discloses that the other free-flowing solid structures such as metal or glass spheres can be used in place of the water-filled capsules ([0042]). The structures disclosed by Wilson et al. are rigid structures and therefore, it would have been obvious to one of ordinary skill in the art to make the covering of the water-filled capsules rigid in order to withstand the freezing-thawing process and pressure applied by the user.

11. Regarding claim 4, the substance is water ([0042]).

12. Regarding claim 7, the bracelet starts out with a square piece of fabric which is then formed in a tube by sewing two of the edges together to form a first seam, inverting the tube as seen in fig. 7c, and finally sewing a seam that closes the tube by sewing edges 116 and 118 together. This technique requires only two seams. Adding the additional layer as made obvious by Rucki requires only one additional seam. An insulating layer covering the bottom half of the fabric layer square can be laid on top of the sheet of fabric and a single seam can attach the insulating layer to the sheet of fabric (along the midline of 113). The remaining steps are performed as disclosed by Wilson et al., with the remaining two seams going through both the insulating layer and the fabric layer. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of manufacturing as disclosed by Wilson et al. with minor changes to account for the presence of an insulating fabric layer on the wrist facing surface of the device since the two devices are similar in structure.

13. Regarding claim 8, two of the three seams separate the wrist-facing side from the outer side. That is, the first seam is at the top of the tube (where 116 and 118 are attached, see fig. 7a) and the other seam is at the bottom of the tube (where the insulating layer was initially attached to the fabric layer square).

14. Regarding claim 9, plural layers are less thermally conductive than a single layer of fabric.

15. Regarding claim 10, Rucki discloses an insulating layer that is heat sealed to the remaining fabric of the cooling device. However, Wilson et al. discloses joining fabric edges by sewing them together and it would be obvious to one skilled in the art to attach the extra layer of fabric by sewing it instead of heat sealing it to the other fabric since the device of Wilson already requires sewing of the device and this would negate the additional procedure of heat sealing materials.

16. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Cipolla and Rucki as applied to claim 1 above, and further in view of Brink (U.S. 5,843,145).

Modified Wilson discloses the invention substantially as stated above, including the presence of water-filled capsules enclosed within the bracelet. Modified Wilson does not expressly disclose that the water-filled capsules are frozen. However, as disclosed by Wilson, the gel that surrounds the capsules advantageously does not become a hard solid after being cooled to below the freezing point of water (col. 3 ll. 60-62), which indicates that the bracelet will be cooled to these temperatures. The water-filled capsules would then be frozen. Furthermore, Brink discloses that it is old and well known in the art to have capsules that hold frozen liquid dispersed in a gel. The capsules serve to provide means for cooling the gel after the cold (such as by a freezer) is no longer applied to the temperature pack (col. 4 lines 20-32 and 38-50).

Therefore, it would have been obvious to one of ordinary skill in the art to freeze the water-filled

capsules as made obvious by Brink in order to provide a means for cooling the gel that surrounds the capsules after the bracelet has been chilled and removed from the cold source.

17. **Claims 11-16 and 19-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (U.S. 2004/0098073) in view of Cipolla (U.S. 5,458,628).

18. Regarding claims 11-14, and 16, Wilson discloses a method comprising enclosing a substance in a capsule ([0042]) in a bracelet, attaching the bracelet to a wrist of a child ([0046], [0047]) and insulating the wrist of the child from a temperature of the substance wherein the capsule is adapted to allow the infant to suck on the capsule through the fabric. The examiner is considering a child to include an age range that includes infants. No ages are indicated in the instant specification for the term "infant" and it seems to the examiner that a 1 yr old, for example, could be called a child or an infant. The presence of the bracelet material around the substance-filled capsule inherently provides some insulation of the wrist of the infant (as opposed to direct contact of the capsule with an infant's wrist). The capsule is adapted to allow the infant to suck on the capsule through the bracelet material. The language "adapted to allow" only necessitates that the capsule is *capable of* being sucked on by an infant. Wilson discloses that the bracelet is made of a polyurethane film. This is being considered a fabric since a fabric can be broadly defined as any pliable material. Polyurethane film is usually non-absorbent but Wilson does not expressly disclose that the polyurethane film used in the invention is non-absorbent

19. However, Cipolla discloses that it is old and well known to cover therapeutic temperature pads with a nonabsorbent material. Such a cover provides for ease of cleanup of the covers and for better heat/temperature and water retention of a pad contained therein. Non-absorbent materials also help avoid staining of the material and foul odors. Using non-absorbent polyurethane film for the device of Wilson would increase the amount of cooling time the

bracelet can provide and would also help avoid contamination of the bracelet material.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Wilson to include non-absorbent polyurethane film such that bracelet material can be easily cleaned and remains cooler longer as made obvious by Cipolla.

20. For claim 12, see [0043]; pre-chilled.

21. For claim 13, see [0045].

22. For claim 14, the bracelet fits snugly on the user's wrist, but is rolled over his or her hand in order to position it onto the wrist. The inner circumference of the bracelet is increased when the bracelet has to enlarge to fit over the user's hand.

23. For 16, see fig. 5a.

24. Regarding claim 15, Wilson does not expressly disclose that the water-filled capsules have a rigid covering. However, Wilson further discloses that the other free-flowing solid structures such as metal or glass spheres can be used in place of the water-filled capsules ([0042]). The structures disclosed by Wilson et al. are rigid structures and therefore, it would have been obvious to one of ordinary skill in the art to make the covering of the water-filled capsules rigid in order to withstand the freezing-thawing process and pressure applied by the user.

25. Regarding claims 19-21, Wilson as modified by the teachings of Cipolla discloses a device comprising a capsule containing a cooled substance ([0042]) and means for attaching the capsule to a wrist of an infant, for insulating the wrist of the infant from the cooled substance, and for allowing the infant to suck on the capsule through the means without allowing the means to absorb the infant's saliva. If the bracelet is placed on an infant, the infant can suck on the capsule through the film. This film is considered a fabric because it is a pliable material. The film also insulates the wrist of the infant from the cooled substance by its presence

between the wrist and the capsule (as opposed to direct contact between the capsule and the infant's wrist). As mentioned above, Cipolla makes obvious the use of a non-absorbent polyurethane film fabric.

26. Regarding claim 20, the means constricts around the wrist of the infant. As seen in fig. 5a, the means fits snugly around the user's wrist. In order to pass over the user's hand, the inner diameter of the bracelet must widen but it returns to its smaller configuration once on the wrist.

27. **Claims 17 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Cipolla as applied to claim 16 above, and further in view of Rucki (U.S. 5,679,052). Modified Wilson discloses the invention substantially as stated above but fails to disclose that the step of insulating the wrist of the infant involves providing the bracelet with plural layers of the non-absorbent fabric at a location where the bracelet contacts the wrist of the infant.

28. However, Rucki discloses that it is old and well known to provide a second layer of material on the patient facing side of the cold therapy device in order to prevent too much cold from being directly applied to the patient (see col. 2 ll. 56-63). Therefore, it would be obvious to one of ordinary skill in the art to apply a second layer of fabric on the wrist facing side of the device of Wilson in order to protect the patient from possible frost-bite. When the second layer of fabric is added, the fabric is thicker on the wrist-facing side of the bracelet than on an outer side of the bracelet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 5/3/2007


GLENN K. DAWSON
PRIMARY EXAMINER